

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

Confirmation No.: NOT ASSIGNED

UBER

Group Art Unit: NOT ASSIGNED

Continuation of Application No. 09/575,809 Examiner: NOT ASSIGNED

Filed: August 28, 2001

Title: MULTI-PATIENT FLUID DISPENSING

August 28, 2001

* * * * *

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents
Washington, D.C. 20231

Sir:

Please enter the following Preliminary Amendment after calculation of the filing fee.

IN THE DRAWINGS:

Please substitute the attached six (6) pages of formal drawings, Figures 1-10 to replace those filed in the parent application No. 09/575,809. A Letter to the Official Draftsperson is attached.

IN THE SPECIFICATION:

Page 1, delete the whole paragraph starting on line 4 and replace it with the following new paragraph:

In U.S. Patent No. 5,569,181 assigned to the same Assignee as the present invention, discussion was undertaken with regard to the problems arising from the potential cross-contamination that can occur with a multi-patient fluid dispensing system. One facet of the system provided involves prevention of contamination of the multi-use segment of the fluid path during the time the system is connected to the patient. The disclosed system utilized one of the two methods: a back flow preventing valve and a sterile filter, or a physical separation

achieved by filling a dose container and separating the dose container from the filling fluid path before connection to the patient.

Page 2, delete the whole paragraph starting on line 9 and replace it with the following new paragraph:

Means of preventing contamination of the fluid path by contaminants other than the patient being injected are presented in U.S. Patent No. 5,806,519. Any of the concepts presented there may be matched with any of the embodiments presented here. The relevant feature is the “per patient” connection.

Page 10, delete the whole paragraph starting on line 20 and replace it with the following new paragraph:

FIG. 8 shows another means of dividing the fluid flow into discrete packets to prevent cross-contamination. This is a variation on the peristaltic idea, where the fluid path splits into two parts. In this figure, fluid is flowing into inlet 6 of chamber 1, its outlet 7 is blocked so the chamber expands and drives the pressure plate 3 against chamber 2. This drives fluid out of chamber 2 and on to the patient. When the pressure plate reaches the maximum designed travel, the inlet valve 4 and outlet valve 5 switch position, allowing chamber 2 to fill and chamber 1 to empty. This allows continuous fluid flow but never permits a continuously open fluid path to exist. It is preferred that the pressure plate upon reaching its end of travel mechanically trigger the inlet valves, and that there be a mechanical linkage between the valves so that they can not both simultaneously open to the same chamber. These controlling strategies could also be performed by the ECS, with redundancy and verification of valve positions. It is possible to extend this concept to using three or more chambers, to get a more even flow.

Page 11, delete the whole paragraph starting on line 12 and replace it with the following new paragraph:

FIG. 10 shows another implementation of packetizing of the fluid flow. In this embodiment it is accomplished via air separation rather than via an intervening solid. After the fluids are mixed, they flow through a back flow valve 23. The fluid then flows through a “y” where it is mixed with packets of air. The air packets separate fluid packets, preventing back diffusion or migration of contaminants if the flow slows or stops. The wall material and

diameter of the tubing is chosen so that the air packets are stable. During operation, fluid and air flow down the line to the air separating chamber 24. Here air separates itself from the fluid and moves upward through a filter 37, returning to be used again. Fluid 38 flows on to the pressurizing pump. The pulsatile air pump 28 could be a peristaltic pump, possibly operating out of phase with the fluid metering pumps so that air is injected when liquid flow is minimum from the metering pumps. After the air is separated from the liquid, the liquid flows through a fluid assurance device 29, is pressurized by the pressurizing pump 33 and flows into the patient 34. The ECS will stop the pumping if the fluid assurance detector detects any air in the line to the pressurizing pump. All of the tubing down stream from the "per patient" connector 39 is disposed of after each patient. If the flow from the metering pumps is sufficiently pulsatile, it may not be necessary to have the air pump. The momentum of flowing fluid can be sufficient to entrain packets of air between packets of fluid.

IN THE CLAIMS:

Please cancel claim 1 without prejudice.

Please add the following new claim(s):

13. An injection apparatus comprising:

a first fluid source;

a second fluid source; and

a fluid path disposed between the first and second fluid sources and a patient, the fluid path comprising:

a mixing device in fluid communication with the first and second fluid sources.

14. The apparatus of claim 13, wherein the fluid path further comprises at least one metering device disposed between the first and second fluid sources and the mixing device.

15. The apparatus of claim 14, further comprising a control device in communication with the metering device.

16. The apparatus of claim 13, wherein the fluid path further comprises a fluid assurance device disposed between the mixing device and the patient.
17. The apparatus of claim 13, wherein the first fluid source comprises a contrast source.
18. The apparatus of claim 13, wherein the second fluid source comprises a diluent source.
19. The apparatus of claim 13, wherein the fluid path comprises a reusable portion and a disposable portion.

REMARKS

Reconsideration and allowance of the present application based on the following remarks is respectfully requested.

Claims 1-12 are deleted. Claims 13-19 are added. Claim 13 is independent.

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned at the telephone number listed below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned "Version with markings to show changes made".

Respectfully submitted,

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Appendix

APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The specification is changed as follows:

Page 1, paragraph starting on line 4, is amended as follows:

In [coping application Serial No. 08/144,845 of even date herewith and] U.S. Patent No. 5,569,181 assigned to the same Assignee as the present invention, discussion was undertaken with regard to the problems arising from the potential cross-contamination that can occur with a multi-patent fluid dispensing system. One facet of the system provided involves prevention of contamination of the multi-use segment of the fluid path during the time the system is connected to the patient. The disclosed system utilized one of the two methods: a back flow preventing valve and a sterile filter, or a physical separation achieved by filling a dose container and separating the dose container from the filling fluid path before connection to the patient.

Page 2, paragraph starting on line 9, is amended as follows:

Means of preventing contamination of the fluid path by contaminants other than the patient being injected are presented in [coping Application No. 08/144,462] U.S. Patent No. 5,806,519. Any of the concepts presented there may be matched with any of the embodiments presented here. The relevant feature is the “per patient” connection.

Page 10, paragraph starting on line 20, is amended as follows:

FIG. 8 shows another means of dividing the fluid flow into discrete packets to prevent cross-contamination. This is a variation on the peristaltic idea, where the fluid path splits into two parts. In this [picture] figure, fluid is flowing into inlet 6 of chamber 1, [it's outlet] its outlet 7 is blocked so the chamber expands and drives the pressure plate 3 against chamber 2. This drives fluid out of chamber 2 and on to the patient. When the pressure plate reaches the maximum designed travel, the inlet valve 4 and outlet valve[s] 5 switch position, allowing chamber 2 to fill and chamber 1 to empty. This allows continuous fluid flow but never permits a continuously open fluid path to exist. It is preferred that the pressure plate upon

reaching its end of travel mechanically trigger the inlet valves, and that there be a mechanical linkage between the valves so that they can not both simultaneously open to the same chamber. These controlling strategies could also be performed by the ECS, with redundancy and verification of valve positions. It is possible to extend this concept to using three or more chambers, to get a more even flow.

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IN THE CLAIMS:

Cancel claim 1. Add claims 13-19.

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LETTER TO THE OFFICIAL DRAFTSPERSON

Hon. Commissioner of Patents
Washington, D.C. 20231

Sir:

Please substitute the attached six (6) pages of formal drawings, Figures 1-10 to replace the informal drawings filed herewith.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By:



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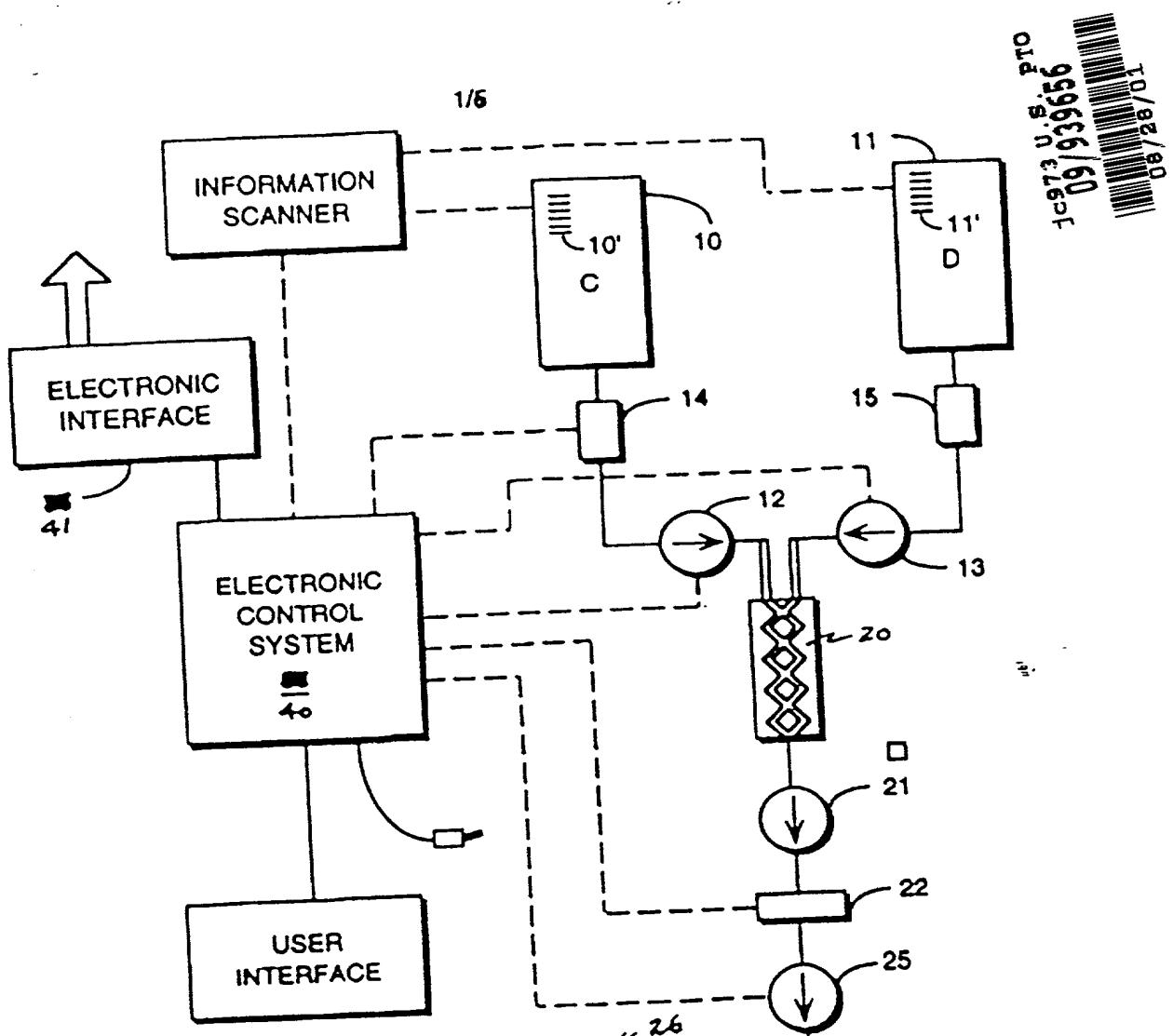
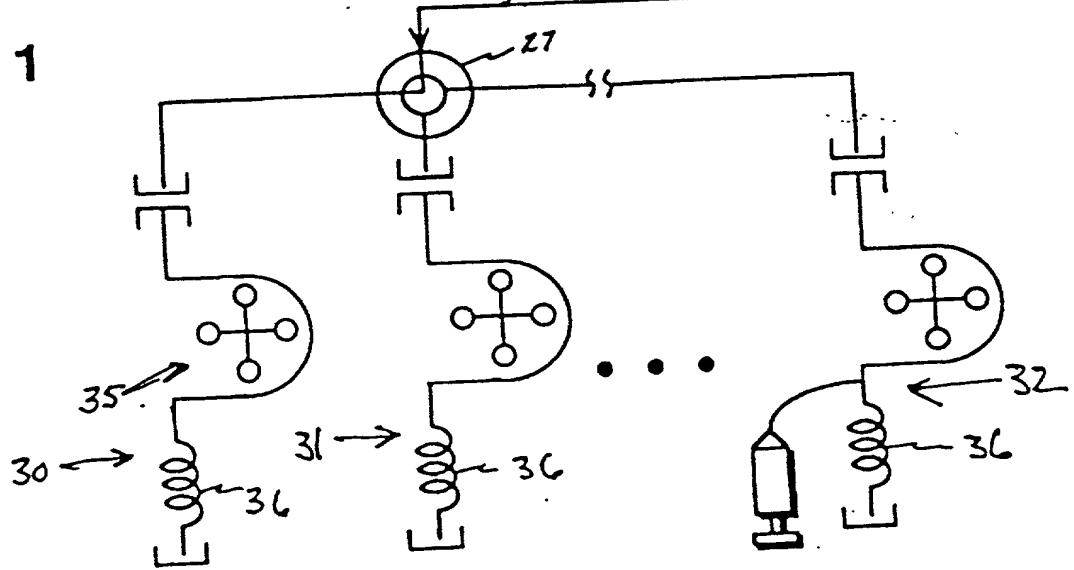


Fig. 1



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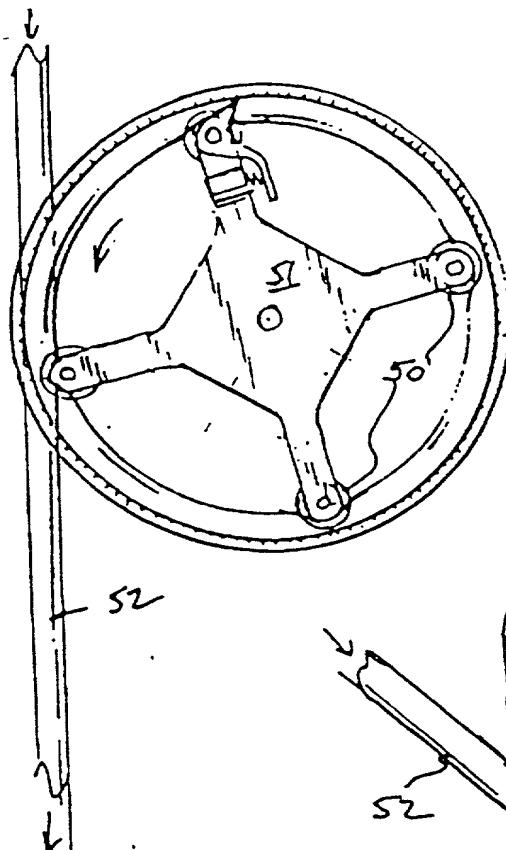


FIG. 2

FIG. 3

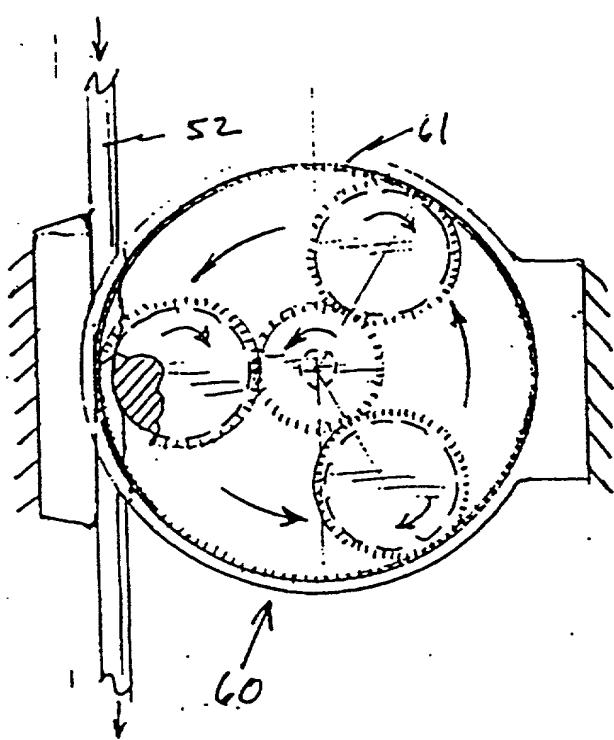
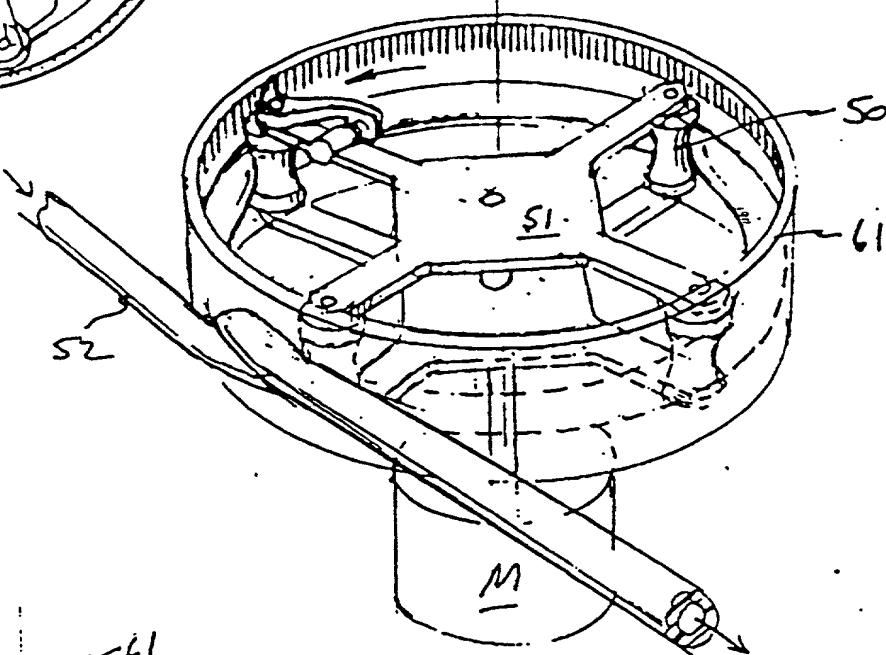
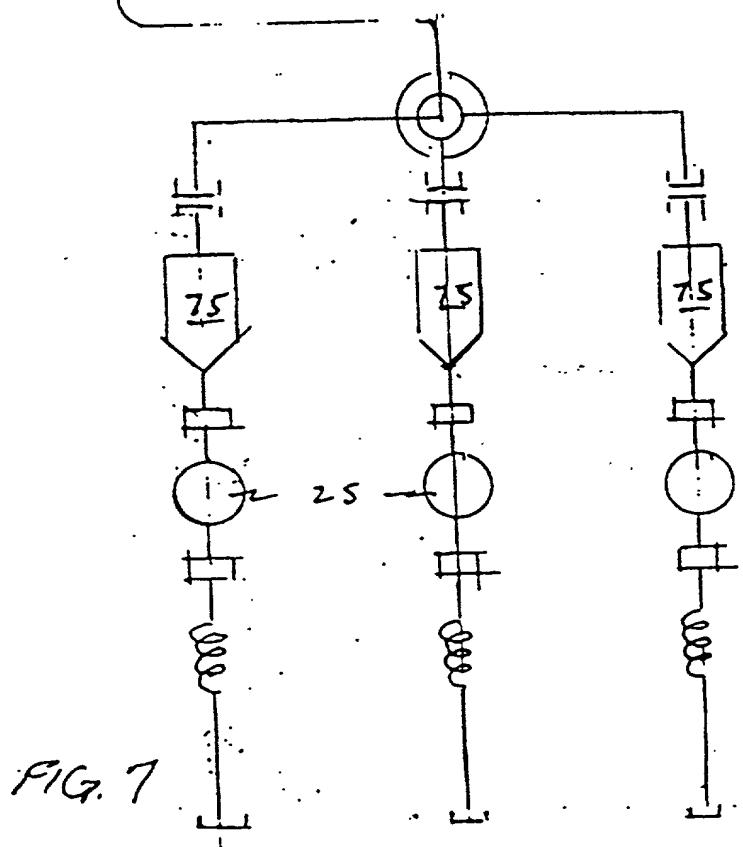
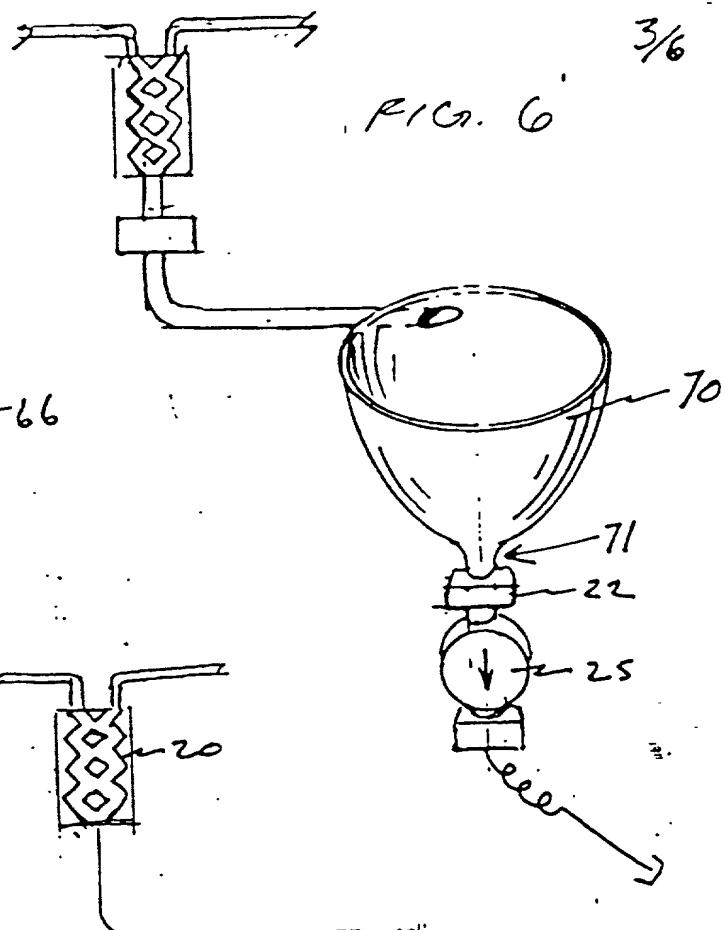
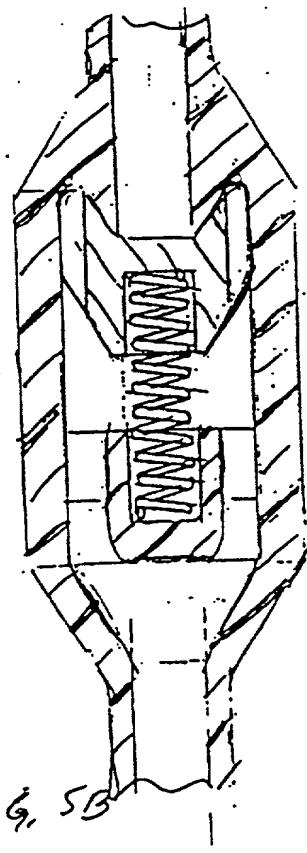
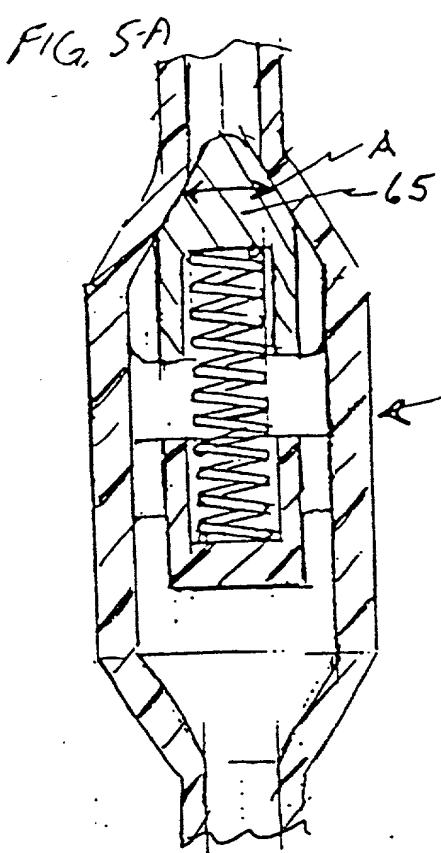


FIG. 4

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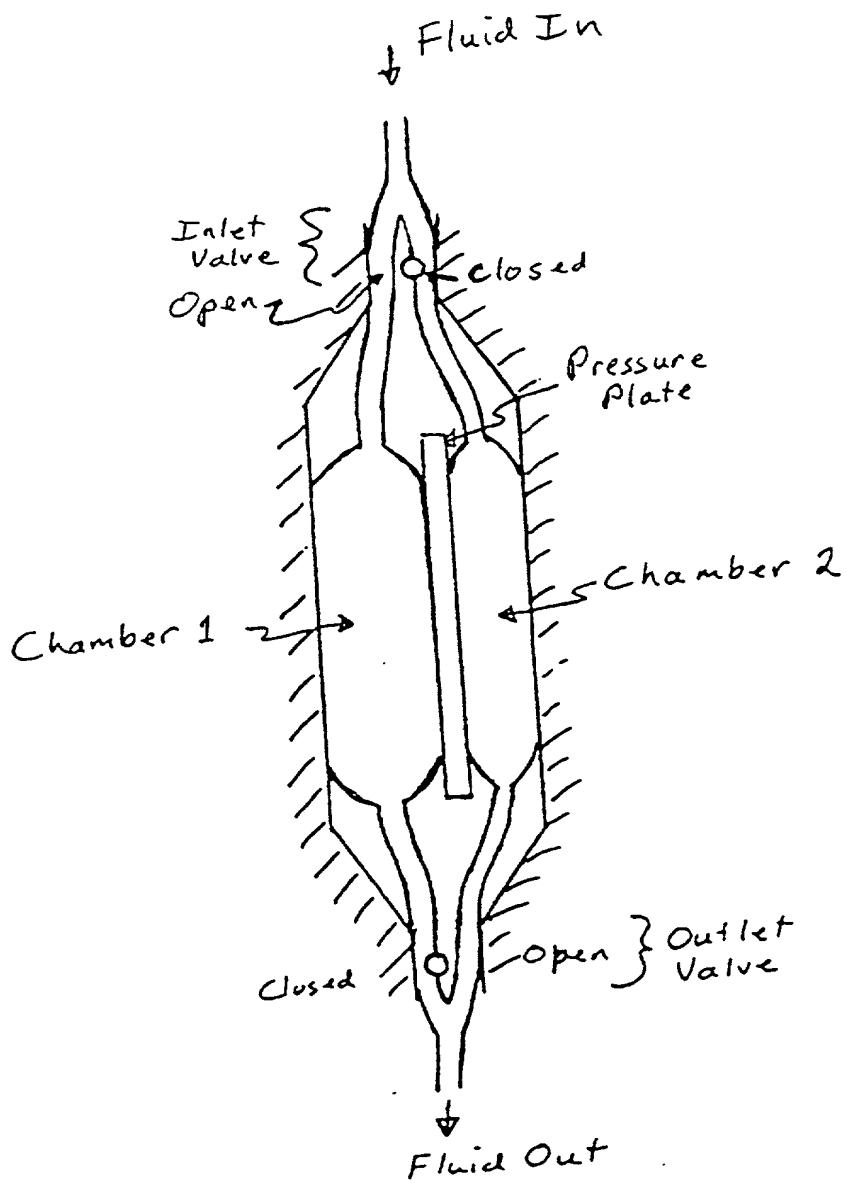


FIG 8

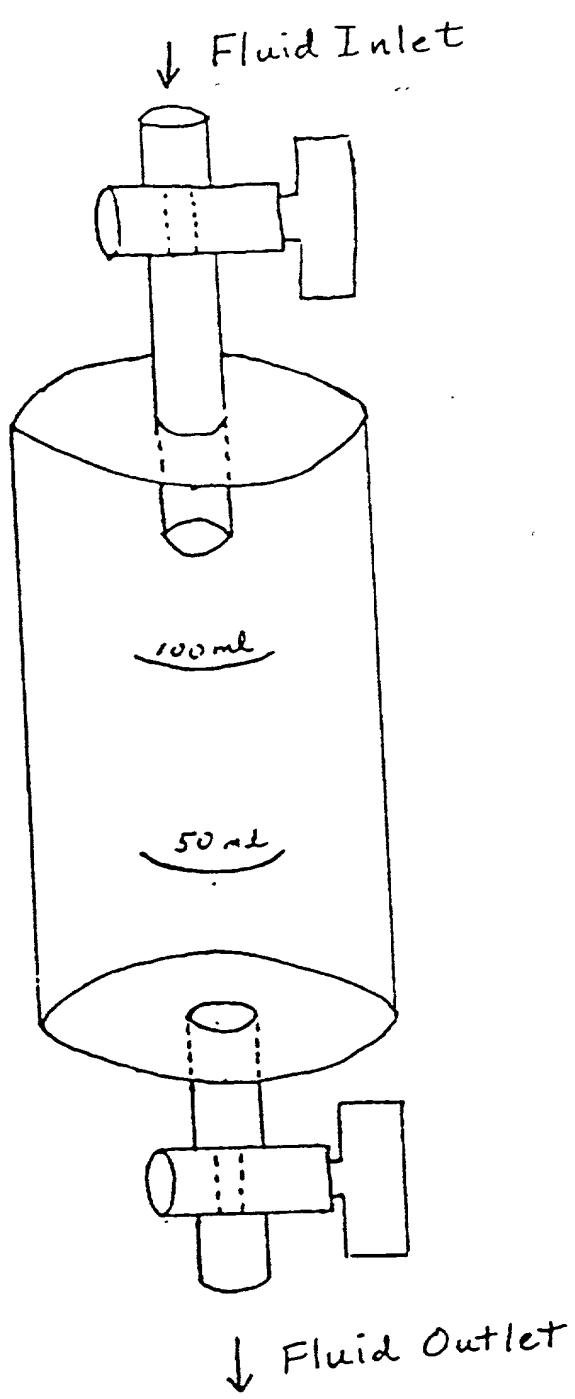


FIG 9

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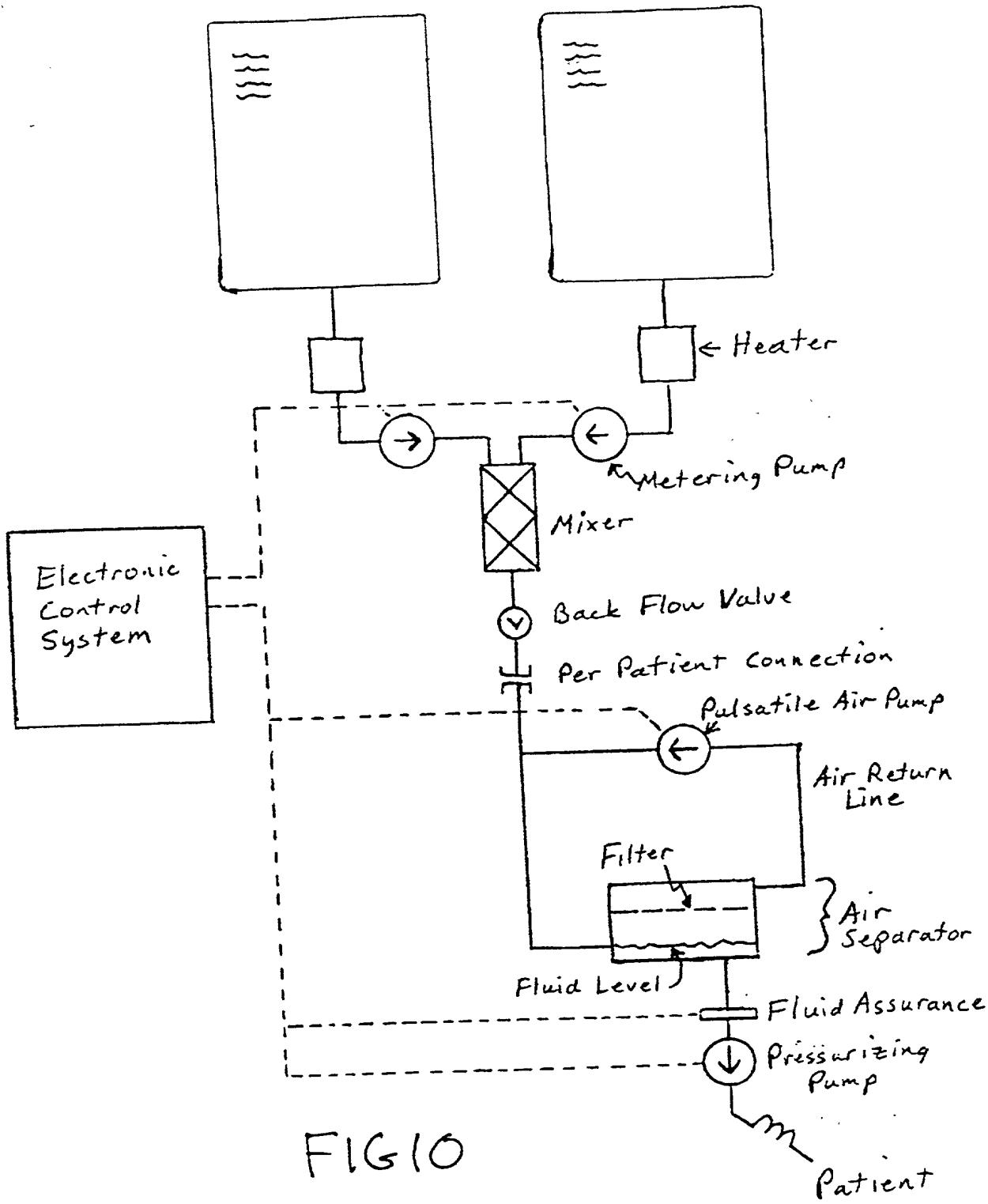


FIG 10